

REMARKS/ARGUMENTS

Claims 20, 67 and 72-85 are pending in the present application. In the Office Action, claims 20, 67 and 72-85 were examined and rejected. In response to the Office Action, claims 20 and 67 have been amended and claims depending thereon have also been amended to correspond with the amendments to claims 20 and 67. No new matter has been added. Reconsideration of the claims as amended is respectfully requested.

Claim Rejections - 35 U.S.C. § 102

Claims 67, 81, 82, 84, and 85 were rejected as being anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 6,165,183 to Kuehn et al. (Kuehn). Such rejections are overcome for at least the following reasons.

Applicants have amended independent claim 67 to more distinctly recite pre-existing features. These amendments do not raise any new issues and thus do not require a new search; rather they merely clarify the features that have been discussed in the previous amendment.

Claim 67 recites a permanently implantable fastener which includes a pair of articulating arms and a pair of superior elements. When the fastener is decoupled or disengaged from the shaft, the articulating arms and superior elements remain permanently implanted in the patient.

Still further, claim 67 recites that the articulating arms cooperate with the superior elements to pinch the valve leaflets therebetween thereby affixing the fastener to the valve leaflets.

The Examiner has based the rejection of claim 67 on FIG. 20 of Kuehn which discloses a grasping tool which is inserted temporarily into a patient in order to grasp the leaflets but is not permanently implanted.

As described in col. 9, line 45 through col. 10, line 3, Kuehn's arms 450 do not grasp the leaflets 122, 124; instead they are merely used to push the leaflets toward the graspers 440. In the device according to Kuehn the leaflets are never pinched between the graspers 440

and the arms 450. Thus, Kuehn fails to disclose or suggest the feature of the claim 67 wherein articulating elements cooperate with the superior elements to pinch the leaflets therebetween.

Moreover, assuming for the sake of argument that the graspers 440 correspond to the superior elements of the claimed invention and the arms 450 correspond to the articulating arms, Kuehn still fails to disclose or suggest the feature of claim 67 wherein the graspers (e.g., the superior elements) are removably connected to the catheter shaft. Instead, Kuehn discloses that the plunger 446, 454 (Figs. 20 and 21) can be removed once the graspers have grasped the leaflets. Thus, the arms 450 but not graspers 440 are disconnected from the catheter (flexible shaft). Additionally, Kuehn suggests that some undisclosed tool may be used to apply a fastener to the leaflets. Thus the graspers 440 and the arms 450 are used to temporarily grasp the leaflets but they do not form part of an implantable fastener. See col. 10, lines 15-25.

For all of these reasons, Applicants respectfully request that the rejection of claim 67 and dependent claims 81, 82, 84 and 85 be reconsidered and withdrawn.

Claim Rejections 35 U.S.C. § 103

Claims 20 and 72-80 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Laufer (U.S. Patent No. 5,609,598), and further in view of Kuehn. Such rejection is traversed for at least the following reasons.

Claim 20 has been amended to recite a system for delivering and permanently implanting a fastener for repairing a valve in a patient's body. Claim 20 has also been amended to further clarify that the fastener is removably coupled to the catheter (or elongate flexible shaft) and is adapted to disengage from the catheter once the fastener is engaged with the valve leaflets thereby permanently implanting the fastener. No new matter has been added. Since claim 20 has been similarly amended as claim 67, substantially all of the reasons for traversing the rejection of claim 67 apply to traversing the rejection of claim 20 over Kuehn.

Laufer fails to disclose or suggest a fastener having both a pair of superior elements and a pair of articulating elements. More particularly, claim 20 recites a pair of articulating arms configured to engage the inferior surfaces of the leaflets and a pair of superior elements configured to engage the superior surfaces of the leaflets.

Laufer only discloses a single set of legs 40, 42 which are adapted to engage a single side of the valve (inferior or superior). See FIG. 5. Even if one were to modify a device according to Laufer to include two sets of legs, they would still only engage a single side of the valve (inferior or superior). Neither the disclosure nor the drawings in Laufer teach or suggest any other embodiment. For at least this reason, Applicants respectfully request that the Examiner reconsider and withdraw the rejection in view of Laufer.

Additionally, it appears that only one of the two arms articulates. Notably, it appears that arm 40 is driven by adjustment mechanism 50 via cord 53 and is the only arm which articulates. Arm 42 is stationary. For this additional reason, Applicants respectfully request that the Examiner reconsider and withdraw the rejection in view of Laufer.

Finally, Laufer discloses a device which is adapted for implantation in the leg and which is not suited for or adaptable for implantation to treat a cardiac valve. Kuehn discloses a tool for grasping valve leaflet and Laufer teaches a clip for treatment of chronic venous insufficiency. The combination of Laufer and Kuehn would yield a clip usable with a tool but it would not disclose or render obvious the fastener of claim 20. Moreover, if Laufer and Kuehn were combined as suggested in the Office Action, valve leaflets would be captured between a pair of superior elements and a pair of articulating elements. Laufer only discloses using a single pair of arms to capture the leaflets. Thus, the use of superior elements from Kuehn would require redesign and reconstruction of Laufer's device as well as a change in the basic principle under which the construction of Laufer's device was designed to operate. Because this changes the principle of operation of the cited reference, the teachings of Laufer are not sufficient to establish *prima facie* obviousness. M.P.E.P. § 2143.01 VI.

For this additional reason, Applicants respectfully request that the Examiner reconsider and withdraw the rejection over Laufer and further in view of Kuehn.

Claim 83 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuehn in view of Oz et al. Claim 83 depends from independent claim 67 which has been distinguished from Kuehn above. Therefore for at least the same reasons discussed about with respect to claim 67, claim 83 is patentably distinguishable from Kuehn and Oz fails to provide

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the elements missing from Kuehn. Applicants therefore respectfully request withdrawal of the obviousness rejection of claim 83 and allowance thereof.

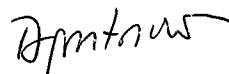
CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

The Examiner is invited to telephone the undersigned attorney to resolve any issues and expedite prosecution of this application.

Respectfully submitted,

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